



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,960	01/30/2004	Evan Gustow	029318-0999	2511
31049	7590	10/20/2006	EXAMINER	
ELAN DRUG DELIVERY, INC. C/O FOLEY & LARDNER LLP 3000 K STREET, N.W. SUITE 500 WASHINGTON, DC 20007-5109			GEORGE, KONATA M	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 10/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/766,960

Applicant(s)

GUSTOW ET AL.

Examiner

Konata M. George

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-92 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17, 24-27, 29-33, 35, 36, 39-65, 77-90 and 92 is/are rejected.
- 7) ☒ Claim(s) 18-23, 28, 34, 37, 38, 66-76 and 91 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/16/04; 9/15/04</u> . | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

Claims 1- 92 are pending in this application.

#### ***Drawings***

1. The drawing(s) filed under 37 CFR 1.184 or 1.152 are accepted by the examiner.

#### ***Information Disclosure Statement***

2. The information disclosure statement (IDS) submitted on August 16, 2004 and September 15, 2004 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

#### ***Specification***

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors (embedded hyperlink and/or other form of browser-executable code). Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Art Unit: 1616

### ***Claim Objections***

4. Claims 12, 54 and 88 are objected to because of the following informalities: claims 12, 54 and 88 contain trademarks. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 39-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant discloses that the topiramate particles together with the stabilizer is contacted for "a time and under conditions", however, it is not taught by the specification what is the time and conditions necessary for contacting the topiramate with the stabilizer.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ

Art Unit: 1616

619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1, 2, 4, 6-8, 10 and 11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 5-7, 9-14 and 18-20 of U.S. Patent No. 6,592,903 in view of US Patent No. 6,696,091.

The applicant and Patent '903 are directed to nanoparticle composition comprising an active agent and a surface stabilizer, wherein the nanoparticles have a particles size of less than 2 microns. The difference between the two is the active agent. The instant invention discloses the active agent as topiramate, whereas, the patent '903 discloses the active agent as a poorly soluble active agent. Claim 14 of '903 teaches classes of these poorly soluble active agents of which anti-epileptics are disclosed. US Patent 6,696,091 is be relied upon to teach that topiramate can be used to treat epilepsy (col. 2, lines 17-20).

Therefore, it would have been obvious to one of ordinary skill in the art to use the teachings of '091, that topiramate can be used treat epilepsy in the invention of '903, which teaches the use of anti-epileptics drugs in nanoparticle compositions.

7. Claims 1-17, 24-27, 29-33, 35, 36, 39-46, 49-56, 58, 65, 77-90 and 92 are provisionally rejected on the ground of nonstatutory obviousness-type double

Art Unit: 1616

patenting as being unpatentable over claims 1, 10, 11, 14, 16, 17, 19, 21-26, 28, 29, 32-38, 41, 46-50, 59, 60, 62, 63, 65, 67-70, 76, 77, 89, 90, 93, 95, 96, 98, 100-104 and 107 of copending Application No. 10/619,539 in view of US Patent No. 6,696,091. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are directed towards a composition comprising an active agent having a particles size of less than 2000 nm and at least one surface stabilizer. The difference between the two is the selection of the active agent and the addition of an osmotically active crystal growth inhibitor in '539. Claim 29 teaches that anti-epileptics can be used as an active agent. US Patent 6,696,091 is be relied upon to teach that topiramate can be used to treat epilepsy (col. 2, lines 17-20). Therefore, it would have been obvious to one of ordinary skill in the art to use the teachings of '091, that topiramate can be used treat epilepsy in the invention of '903, which teaches the use of anti-epileptics drugs in nanoparticle compositions. With respect to the addition of an osmotically active crystal growth inhibitor, the composition of the instant application is not limited to what is being claimed. The open language of comprising allows additional ingredients to be present. Furthermore, the osmotically active crystal growth inhibitors as claimed such as glycerol, can be used as a surface-active agent (see claim 17 of '405).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1, 2, 4, 6-8, 10 and 11 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,592,903.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as

Art Unit: 1616

prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

9. Applicant has provided evidence in this file showing that the invention was owned by, or subject to an obligation of assignment to, the same entity as 10/619,539 at the time this invention was made, or was subject to a joint research agreement at the time this invention was made. However, reference 10/619,539 additionally qualifies as prior art under another subsection of 35 U.S.C. 102, and therefore, is not disqualified as prior art under 35 U.S.C. 103(c).

Applicant may overcome the applied art either by a showing under 37 CFR 1.132 that the invention disclosed therein was derived from the invention of this application, and is therefore, not the invention "by another," or by antedating the applied art under 37 CFR 1.131.

10. Claims 1-17, 24-27, 29-33, 35, 36, 39-46, 49-56, 58, 65, 77-90 and 92 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 10/619,539 which has a common inventors and assignee with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if published or patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future publication or patenting of the conflicting application.



Art Unit: 1616

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131. This rejection might also be overcome by showing that the copending application is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

***Allowable Subject Matter***

11. Claims 18-23, 28, 34, 37, 38, 66-76 and 91 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

12. Claims 1-17, 24-27, 29-33, 35, 36, 39-65, 77-90 and 92 are rejected.

Art Unit: 1616

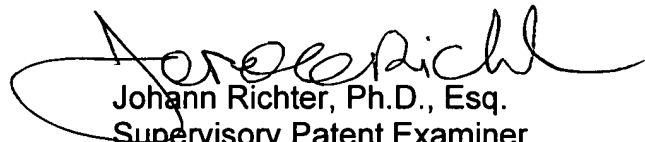
***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konata M. George  
Patent Examiner  
Technology Center 1600

  
Johann Richter, Ph.D., Esq.  
Supervisory Patent Examiner  
Technology Center 1600